UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,685	06/16/2000	Kieran P. J. Mirphy	1960.196	2321

9896 7590 08/08/2002

COOK GROUP PATENT OFFICE
P.O. BOX 2269
BLOOMINGTON, IN 47402

EXAMINER
ROBERT, EDUARDO C

ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 08/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Supplemental **Office Action Summary**	Application No. 09/594,687 5/14/02	Applicant(s) Murphy, Kieran
	Examiner Eduardo C. Robert	Art Unit 3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 16 June 2000 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Drawings

The drawings are objected to because they do not include certain Figures mentioned in the description. The following figures mentioned in the brief description of the drawings are not included in the drawings: Figures 2 and 3. Correction is required.

Applicant is required to submit a proposed drawing correction in response to this Office Action. Any proposal by the applicant for amendment of the drawings to cure defects must consist of two parts:

a) A separate letter to the Draftsman in accordance with MPEP § 608.02(r); and

b) A print or pen-and -ink sketch showing changes in red ink in accordance with MPEP § 608.02(v).

IMPORTANT NOTE: The filing of new formal drawings to correct the noted defect may be deferred until the application is allowed by the examiner, but the print or pen-and-ink sketch with proposed corrections shown in red ink is required in response to this Office Action, and may not be deferred.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 14, line 1, "said hardenable liquid biomaterial" lacks a prior antecedent.

In claim 17, line 4, "a second tray of components performing a second vertebroplasty" is indefinite because it is unclear how a tray of components is capable of performing a

vertebroplasty. It appears that -- for -- should be inserted before "performing" so that the indefiniteness be solved and will be considered as such for examination purposes.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-19, as understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Lazarus, et al.

Lazarus, et al. disclose a kit 10 comprising a first tray 10a of components and a second tray 10b of components. The first and second tray are individually assembled and packaged and are kept sterile until use.

Claims 17-18, as understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Partika, et al.

Partika, et al. disclose a kit comprising a first and second tray of components (see figure 2) which are individually assembled and packaged and kept sterile until use.

Applicant is reminded that an anticipation under 35 U.S.C. 102(b) or 102(e) is established **when a single prior art reference discloses, either expressly or under principles of inherency, each and every element of a claimed invention**. *RCA Corp. v. Applied Digital Data System, Inc.*, 730 F.2d 1440, 221 USPQ 385 (Fed. Cir. 1984). Furthermore, **it is well settled that the law of anticipation does not required that the reference teach what appellant is teaching**

or has disclosed, but only that the claims on appeal "read on" something disclosed in the reference, i.e. all limitation of the claims are found in the reference. *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1083). Moreover, it is not necessary for the applied reference to expressly disclose or describe a particular element or limitation of a rejected claim word for word as in the rejected claim so long as the reference inherently discloses that element or limitation. *Standard Havens Products Inc. v. Gencor Industries Inc.*, 953 F.2d 1360, 21 USPQ 2d. 1321 (Fed. Cir. 1991).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Folkman in view of Shanley, et al.; Macleod, et al.; Smith, et al.; Arlers; Racz; Jiang, et al.; Singer; Draenert; Haynie; Hertzman, et al.; and Baker.

Folkman discloses a tray for medical equipment. Folkman discloses the claimed invention except for the tray having local anasthesia, local anasthesia aspiration syringe, local anasthesia aspiration needle, local anasthesia, injection needle, liquid monomer, monomer aspiration needle, monomer aspiration syringe, mixing bowl, mixing spatula, polymer powder, opacifier, scalpel, and needle. Shanley, et al. disclose that kits or tray can have a local anasthesia injection needle 6. Macleod, et a. disclose that kits or tray can have a local anasthesia compound.

Smith, et al. disclose a aspiration syringe for fluids (see col. 9, lines 9-11). Arlers discloses another aspiration syringe. Racz discloses an aspiration needle for fluids. Jiang, et al. disclose that liquid monomers can be on a kit or tray. Singer discloses another aspiration needle. Draenert discloses a mixing bowl and polymeric powder. Haynie discloses that a tray or kit can have a mixing spatula. Hertzman, et al. disclose that a tray or kit can have a scalpel. Baker discloses that a tray or kit can have opacifier. As shown above, the individual components of applicant's tray or kit are known in the prior art and because the individual components are known in the prior art, it would have been obvious to one of ordinary skill in the art at the time the invention to have any of these components available at the same time, i.e. as in a "kit", such as during surgery the surgeon can select the appropriately component for the particular procedure and patient. In other words, the individual components of applicant's kit or tray already available as prior art; merely combining the components under the rubric of a "kit" or "tray" does not result in a novel invention, even taken as a whole. It is contemplated that the surgeon or any medical practitioner can meet applicant's claimed invention by simply purchasing the Shanley, et al., Macleod, et al., Smith, et al., Arlers, Racz, Jiang, et al., Singer, Draenert, Haynie, Hertzman, et al., and Baker components, and placing these components in proximity to each other or on a medical tray, e.g. Folkman's tray, so as to fall under the rubric of a kit. Here, the novelty of the invention must reside in its whole, i.e. the kit or tray, being grater than the sum of its parts, since the parts or components of the invention are already known in the art. With regard to claim 13, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the combination of Folkman as modified by Shanley, et al.; Macleod, et al.; Smith, et al.; Arlers; Racz; Jiang, et al.; Singer; Draenert; Haynie; Hertzman, et al.; and Baker with the

polymeric powder being methylmethacrulaty, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Scribner et al.; Vagley ; Barney ; Villarreal ; Misra ; Glassman ; Estes ; Cooley, et al. ; Stevens; and Meyers are cited art of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 703-308-2698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C. Robert
May 9, 2002